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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,341	06/09/2006	Sung Youb Jung	Q115525	7156

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EXAMINER	
DAHLE, CHUN WU	

ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
05/27/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/535,341	JUNG ET AL.	
	Examiner	Art Unit	
	CHUN DAHLE	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 15* is/are pending in the application.

4a) Of the above claim(s) *8-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7, 13, and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid*

DETAILED ACTION

1. Applicant's amendments, filed on April 27, 2010, are acknowledged.

Claim 14 has been canceled.

Claims 1-13 and 15 are pending.

Claims 8-12 stand withdrawn from further consideration by the Examiner, under 37 C.F.R. 1.142(b), as being drawn to nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 15, 2008.

Claims 1-7, 13, and claim 15 are currently under consideration as they read on the elected invention of an Fc fragment and SEQ ID NO:8.

2. This Office Action will be in response to applicant's arguments, filed on April 27, 2010.

The rejections of record can be found in the previous Office Action, mailed on June 10, 2008, March 4, 2009, and October 27, 2009.

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Three amino acid sequences are disclosed in paragraph 1 on page 48 of the specification. However, the sequences fail to comply with the Sequence Rules.

Applicant is reminded of the Sequence Rules which require a submission for all sequences of 10 or more nucleotides or 4 or more amino acids (see 37 CFR 1.1821-1.1825) and is also requested to carefully review the submitted specification for any and all sequences which require compliance with the rules.

Applicant is required to review the instant application for compliance with the requirements of applications which contain sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821-1.825.

4. In view of applicant's amendment to the claims, only following rejection has been maintained.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-7, 13, and 15 stand rejected under 35 U.S.C. 102(e) as being anticipated by Kostenuik et al. (US Patent 6,756,480, reference of record) for reasons of record.

The prior Office Action, mailed on October 27, 2009, states

"*Kostenuik et al. teach parathyroid hormone peptide (PHP) covalently linked to an Fc domain via a linker (e.g. see claims 1-3). Kastenuik et al. further teach that said linker can be non-peptide linker such as PEG linker (e.g. see Linkers defined on columns 33-34). Further, Kastenuik et al. teach that said Fc domain can be human IgG1, 2, 3, or 4 and aglycosylated (e.g. see columns 8-9 and 31-32). Furthermore, Kastenuik et al. teach pharmaceutical composition comprising said PHP covalently linked to an Fc (e.g. columns 39-40). Given that the recited SEQ ID NO:8 is the amino acid sequence of the Fc region of human mature IgG4, the prior art Fc region from human IgG4 would read onto the instant claim 7 encompassing SEQ ID NO:8.*

Therefore, the reference teachings anticipate the claimed invention."

Applicant's arguments, submitted on April 27, 2010, have been fully considered but have not been found persuasive.

Applicant argues that the relevant portion of Kostenuik et al. provides a long list of linkers including PEG. Applicant argues that the prior art does not provide any working example of PEG covalently linked to a drug through a non-peptide linker or any embodiment thereof. Applicant asserts that the prior art teach a non-peptide linker should be used together with additional vehicle such as a polymer and a peptide linker would be used together with a peptide vehicle with is in the Fc domain. Applicant asserts that the claimed invention distinguishes from the prior art in that the instant claims are drawn to non-peptide linkers. Applicant asserts that the present invention encompasses an Fc fragment and the physiologically active polypeptides are covalently linked via a non-peptide polymers.

Applicant argues that the prior art fails to provide guidance or motivation to combine the elements.

As such, applicant argues that the rejection should be withdrawn.

This is not found persuasive for following reasons:

Contrary to applicant's arguments regarding motivation to combine, it is noted that such arguments are irrelevant to 35 U.S.C. 102 rejections and thus cannot overcome a rejection so based.

Further, in contrast to applicant's arguments relying upon the lack of working examples of the prior art, it is noted that under 35 USC 102(e), the entire disclosure of a U.S. patent or an application publication when examining a PG-PUB application having an earlier filing date can be relied on to reject the claims. See MPEP 2136.02.

Here, the teachings of Kostenuik et al., when considered in its entirety, would encompass a prathyroid hormone peptide (PHP) covalently linked to an Fc region (e.g. IgG4 Fc region) via non-peptide linker including PEG (e.g. see linkers defined on columns 33-34). Specifically, Kostenuik et al. claims

"1. A polypeptide comprising a parathyroid hormone (PTH) peptide and a Fc domain, wherein said Fc domain is covalently attached to the C-terminus of said PTH peptide.

2. The polypeptide of claim 1 further comprising a linker attaching said Fc domain to said PTH peptide."

On columns 33-34, Kostenuik et al. define that a linker can be PEG.

Therefore, the prior art's polypeptide comprising a PTH and a Fc domain wherein said Fc domain is covalently attached to the PTH via a linker including PEG would meet the claimed limitation of an Fc fragment covalently linked to a drug through a non-peptide linker including PEG.

Therefore, applicant's arguments have not been found persuasive.

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225

USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-7, 13, and 15 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of copending USSN 10/535,231 and claims 1-19 and 27-45 of copending USSN 10/535,232 for reasons of record.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Given that no terminal disclaimer signed by the assignee and fully complied with 37 CFR 3.73(b) was filed, the provisional rejection on the ground of nonstatutory obviousness-type double patenting is maintained.

9. Claims 1-7, 13, and 15 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 and 24 of copending USSN 11/747,153 and claims 1-25 of copending USSN 11/910,962 and claims 1-26 and 33 of copending USSN 11/947,697 for reasons of record.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Given that no terminal disclaimer signed by the assignee and fully complied with 37 CFR 3.73(b) was filed, the provisional rejection on the ground of nonstatutory obviousness-type double patenting is maintained.

10. Claims 1-7, 13 and 15 are directed to an invention not patentably distinct from claims 1-19 and 24 of commonly assigned copending USSN 11/747,153 and claims 1-25 of commonly assigned copending USSN 11/910,962 and claims 1-26 and 33 of commonly assigned copending USSN 11/947,697 for reasons stated above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned USSNs 11/747,153, 11/910,962, and 11/947,697, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

11. No claim is allowed.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Dahle whose telephone number is 571-272-8142. The examiner can normally be reached on 8:30-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Ram Shukla can be reached 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Chun Dahle
Patent Examiner
TC 1644

/Maher M. Haddad/
Primary Examiner,
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